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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,899	10/12/2001	Douglas J. Goetz	D6379	1164

7590

10/22/2002

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EXAMINER

BELYAVSKYI, MICHAEL A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 10/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/975,899

Applicant(s)

GOETZ ET AL.

Examiner

Michail A Belyavskyi

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2002 and 15 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) 1-5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

Art Unit: 1644

#### DETAILED ACTION

1. The examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Michail Belyavskyi, Group Art Unit 1644, Technology Center 1600

*Claims 1-7 are pending.*

Applicant's election without traverse of Group IX, claims 6 and 7 in Paper No. 4 and further election of cancer as species of pathophysiological state and biodegradable particles as species of the biomolecular carrier in paper NO. 6 are acknowledged.

Upon further consideration, Group X, claims 6 and 7, drawn to method of treating pathophysiological state, comprising administering biodegradable particles that bind to P-selectin, wherein targeting molecule include antibody or antibody fragments that bind P-selectin was rejoined with the elected Group IX.

Claims 1-5 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

Claims 6-7 drawn to a method of treating cancer, comprising administering biodegradable particles that binds to ICAM-1 or P-selectin, wherein targeting molecule include antibody or antibody fragments that bind ICAM-1 or P-selectin are under consideration in the instant application.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112.

*The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*

3. Claims 6 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is indefinite and ambiguous in the recitation of "the biomolecular carrier of Claim 1" because Claim 1 is non-elected.

Art Unit: 1644

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

*(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 37(c) of this title before the invention thereof by the applicant for patent.*

Claims 6 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Hallahan et al., (US Patent NO: 6,159,443).

Hallahan et al., teach a method of treating cancer, the method comprising steps of exposing a target tissue or organ to the ionizing radiation and administering a delivery vehicle (see entire document, Abstract and column 13, lines 24-30 in particular). Hallahan et al., teach that delivery vehicle is a biodegradable particles bearing molecules that bind to a cellular adhesion molecule expressed on endothelial cells (column 7-8 in particular). Hallahan et al., also teach that said molecules are antibody or antibody fragments that specific for P-selectin (column 8, lines 17-21 in particular). Hallahan et al., also teach that there is a substantial need for an improved method for a selective delivery of therapeutic or imaging agents using biomolecular carrier bearing antibodies to cellular adhesion molecule that overexpressed on endothelial cells (column 2, lines 36-45 in particular) after irradiation.

The reference teachings anticipate the claimed invention.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

*(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.*

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hallahan et al., (US Patent NO: 6,159,443) in view of the know fact disclosed in the specification on pages 4, lines 15-20; 5, lines 1-5; and 10, lines 12-20 and Mastrobattista et al., (Biochim. Biophys. Acta, 1999, 1419, 353-363).

Art Unit: 1644

The teaching of Hallahan et al., was discussed, *supra*

Hallahan et al. does not teach biomolecular carrier bearing antibodies that specific to ICAM-1.

The known fact disclosed in the specification on pages 4, lines 15-20 ; 5, lines 1-5; and 10, lines 12-20 teaches that exposure of diseased tissue to irradiation causes an increase expression of several cellular adhesion molecule on endothelial cells, including P-selectin and ICAM-1.

Mastrobattista et al. teach biomolecular carrier, bearing anti ICAM-1 antibodies (see entire document, Abstract in particular). Mastrobattista et al. also teach that biomolecular carrier, bearing anti ICAM-1 antibodies can be effectively used to delivery drugs to the sites where the expression of ICAM-1 is increase.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply the teaching of Mastrobattista et al. and known fact disclosed in Specification on pages 4, lines 15-20 ; 5, lines 1-5; and 10, lines 12-20 to those of Hallahan et al. and substitute biomolecular carrier bearing antibodies to one cellular adhesion molecule(P-selectin) to biomolecular carrier bearing antibodies to another cellular adhesion molecule (ICAM-1), since the expression of any one of them would be enhanced in target tissue after irradiation, to obtain a claimed method of treating cancer, comprising the steps of irradiating a target tissue or organ and administering the biomolecular carrier bearing antibodies that specific to ICAM-1.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so, because Mastrobattista et al. teach that biomolecular carrier, bearing anti ICAM-1 antibodies can be effectively used to delivery drugs to the sites where the expression of ICAM-1 is increase and known fact disclosed in Specification on pages. teaches that in response to irradiation there is an enhanced expression of several cellular adhesion molecule on endothelial cells, including P-selectin and ICAM-1 and Hallahan et al., teach that there is a substantial need for an improved method for a selective delivery of therapeutic or imaging agents using biomolecular carrier bearing antibodies to cellular adhesion molecule that overexpressed on endothelial cells.

From the combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

7. No claim is allowed.

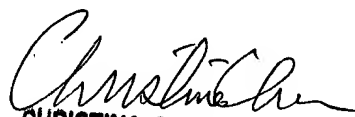
Art Unit: 1644

8. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is (703) 308-4232. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Michail Belyavskiy, Ph.D.  
Patent Examiner  
Technology Center 1600  
October 21, 2002

  
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SUPERVISORY PATENT EXAMINER  
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